UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
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TOXIC SUBSTANCES

July 9, 1999
MEMORANDUM

SUBJECT: **Coumaphos**. Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996.
PC Code: 036501
DP Barcode: D257482

FROM: Christina Jarvis, EPS
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Al Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

TO: Robert McNally, Branch Chief
Special Review Branch
Special Review and Reregistration Division (7508W)

Background:

The FQPA Safety Factor Committee recommended that the 10X FQPA safety factor for the organophosphorus acaricide coumaphos be reduced to 3X, due to data gaps for the acute and subchronic neurotoxicity studies in the rat. Bayer Corporation has since submitted these neurotoxicity studies; they have been reviewed and are found to be acceptable. Since Bayer Corporation has satisfied the requirements for the acute and subchronic neurotoxicity studies in the rat, the FQPA Safety Factor Committee has reduced the FQPA safety factor to 1X. The Hazard Identification Assessment Review Committee (HIARC) has also determined that the acute neurotoxicity study in the rat is more appropriate for the acute dietary risk assessment than the 13-week dietary study in rats, since the endpoint (cholinesterase inhibition) is seen following a single oral dose, rather than the previous endpoint (cholinesterase inhibition), which is measured at the 21-day time point.

The HIARC recommended the toxicity endpoint from the 5-day dermal toxicity study be

used for short-term dermal risk assessment purposes instead of the toxicity endpoint from the 21-day dermal study, as some handlers are exposed to coumaphos for less than 21 days (based on some of the use-patterns and potential exposure scenarios for coumaphos). Therefore, a shorter-term exposure dermal toxicity study is more appropriate to assess worker risk in these cases. The endpoint from the 21-day dermal study is still appropriate for the intermediate-term risk assessment (for handlers whose exposure to coumaphos is 7-180 days per year). Only the following four exposure scenarios are considered intermediate-term exposure: mixing/loading liquids and wettable powders for hydraulic type dip vats (cattle only), and mixing/loading liquids and wettable powders for swim type dip vats (cattle only).

This memorandum updates the HED dietary and occupational risk assessments for coumaphos. Attachments include the Hazard Identification Assessment Review Committee (HIARC) reports (N. Paquette memo, 05/12/99 and 06/25/99), the Dietary Exposure report (S. Mason and C. Jarvis memo, 06/01/99 and 07/09/99), the FQPA Safety Factor Committee report (B. Tarplee memo, 06/01/99), the Occupational Exposure Assessment (R. Sandvig memo, 06/29/99), and the Tier 1 Drinking Water Assessment (J. Hetrick memo, 06/16/99).

I. Executive Summary

Coumaphos, an organophosphorus acaricide, is applied directly to livestock animals for the control of arthropod pests. Registered primarily by Bayer Corporation, coumaphos is formulated as a dust, a ready-to-use dust, a wettable powder, an emulsifiable concentrate, a flowable concentrate, and a pressurized liquid. Coumaphos may be applied using a high or low pressure hand wand, foam spray can, dip vats, mechanical dusters, shaker cans, dust bags, ready-to-use dust containers, and back oilers/rubbers. There are no registered uses on agricultural crops or in/around residences.

The critical toxic endpoints selected for risk assessment are based primarily on red blood cell, brain, and plasma cholinesterase inhibition. Coumaphos is not carcinogenic or mutagenic. Dermal and inhalation absorption are both assumed to be 100%.

An uncertainty factor (UF) of 100 was applied to the risk assessment to account for inter- and intraspecies variation. An extra UF of 3 was applied to the acute dietary risk assessment and the short- and intermediate-term inhalation assessment to account for the lack of a NOAEL. The FQPA Safety Factor (as required by the Food Quality Protection Act of August 6, 1996) was reduced to 1X for the dietary risk assessment.

The revised acute dietary risk assessment indicates no risk of concern for any population subgroup, with an acute dietary risk estimate of 21% of the Population Adjusted Dose (PAD)[1] for the highest exposed subpopulation (children 1-6), and a chronic dietary risk estimate of 43% of the PAD for the highest exposed subpopulation (children 1-6). Calculated risks are based on a revised acute PAD of 0.007 mg/kg/day and a revised chronic PAD of 0.0003 mg/kg/day.

Potential exposures from coumaphos residues in drinking water were assessed using Tier 1 modeling techniques (GENEEC and SCI-GROW). Acute exposure from coumaphos in

[1] PAD = Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

drinking water (surface and ground water) is not a risk of concern. Chronic exposure from coumaphos in drinking water exceeds HED's level of concern for the U.S. general population, children 1-6, and infants (<1 year).

Based on HED's revised occupational risk assessment, short- and intermediate-term risk estimates for occupational workers exceed HED's level of concern for 16 of 17 scenarios at the baseline level of exposure. Six of these scenarios cannot be further mitigated with additional PPE for the short-term duration. For the intermediate-term exposure duration, estimates for occupational workers exceed HED's level of concern for all scenarios, at both the baseline and the additional PPE levels of exposure.

Both short- and intermediate-term dermal and inhalation endpoints were based on cholinesterase inhibition; therefore, it is appropriate to combine the dermal and inhalation Margins of Exposure (MOEs). Since the dermal and inhalation acceptable MOEs are different (100 and 300, respectively) an Aggregate Risk Index (ARI)[2] was calculated, as opposed to a total MOE. To be acceptable, the ARI must be equal to, or greater than, one. For scenarios where there were no inhalation data, the dermal and inhalation MOEs were not aggregated, and the acceptable MOE remains 100.

ARIs at baseline range from 0.0007 to 0.092 for short-term exposure and from 0.001 to 0.002 for intermediate-term exposure. At the PPE level (personal protective equipment), ARIs range from 0.15 to 0.49 for short-term exposure and from 0.014 to 0.33 for intermediate-term exposure.

The current methods used to apply coumaphos do not appear to incorporate engineering controls. The Agency seeks information on any current or feasible engineering control to mitigate risk to handlers, such as closed mixing/loading systems or automated application spray systems. HED has determined that there is likely to be some post-application exposure to people contacting treated animals immediately after application is complete. However, the amount of exposure is likely to be substantially lower than exposure to handlers. Therefore, no post-application exposure data are required.

An aggregate risk assessment (food + drinking water) was conducted for acute and chronic exposure from coumaphos. Acute aggregate risks are below HED's level of concern. Chronic dietary risk estimates are below HED's level of concern; however, when exposure through dietary and drinking water are aggregated, the aggregate risk exceeds HED's level of concern.

II. Hazard Identification

A. Hazard Profile

The toxicology database for coumaphos is complete with the submission of the acute and subchronic neurotoxicity studies in the rat. In summary, coumaphos is highly acutely toxic via the oral, dermal, and inhalation routes of exposure. Coumaphos is not a dermal sensitizer or a dermal

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[2] $ARI = 1/[(1/(Dermal\ MOE_{calculated}/Dermal\ MOE_{acceptable})) + (1/(Inhalation\ MOE_{calculated}/Inhalation\ MOE_{acceptable}))]$

irritant.

The critical toxic endpoints selected for risk assessment are based primarily on red blood cell, brain, and plasma cholinesterase inhibition. Coumaphos is classified as a Group E chemical, indicating that it is "Not Likely" to be carcinogenic in humans via relevant routes of exposure. This classification is based on adequate studies in two animal species. No evidence of mutagenicity was seen in any study.

Dermal absorption is estimated to be 100%. This estimate is based on the observation that erythrocyte cholinesterase inhibition is observed in both oral and dermal rat studies at similar dose levels.

B. Endpoint Selection

Table 1 lists the endpoints selected for risk assessment purposes. The acute neurotoxicity study used for the acute dietary risk assessment is a more appropriate exposure scenario than the 13-week dietary study in rats, which showed effects (red blood cell cholinesterase inhibition) only after 21 days of dosing. The acute neurotoxicity study showed effects after a single oral (gavage) dose (N. Paquette memo, 05/12/99).

For short-term dermal risk assessment purposes, the toxicity endpoint from the 5-day dermal toxicity study in the rat replaces the toxicity endpoint from the 21-day dermal toxicity study in the rat. Since workers will be exposed to coumaphos for less than 21 days for some of the use-patterns and potential exposure scenarios associated with coumaphos, a shorter-term exposure dermal toxicity study is more appropriate for assessing worker risk. The 5-day dermal toxicity study better characterizes the shape of the dose response for the critical effect (plasma, RBC, and brain ChE inhibition) than the 2-day dermal study; in addition, the toxicity effect from the 2-day study will underestimate the worker risk because short-term exposure is defined as exposure to a pesticide from one to seven days.

Since the HED Safety Factor Committee reduced the FQPA safety factor to 1X, the acute and chronic RfD are identical to the Population Adjusted Dose (PAD) for the acute and chronic dietary endpoints.

Table 1: Endpoints selected for risk assessment purposes

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	LOAEL= 2.0 UF = 300	Plasma ChE inhibition in females and RBC ChE Inhibition in both male and female rats	Acute Oral Neurotoxicity in Rats
	Acute RfD (PAD) = 0.007 mg/kg/day		
Chronic Dietary	NOAEL=0.025 UF = 100	Plasma and RBC ChE Inhibition in both male and female dogs	Chronic Toxicity -Dog
		Chronic RfD (PAD) = 0.0003 mg/kg/day	

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Short-Term (Dermal)	NOAEL=5.0 UF = 100	Brain ChE Inhibition in female rats	5-Day Dermal Study in Female Rats
Intermediate-Term (Dermal)	NOAEL=0.5 UF = 100	RBC ChE Inhibition in female rats	21-Day Dermal Study in Rats
Long-Term (Dermal)	None	The use pattern and exposure scenario does not indicate a need for long term risk assessment	
Short-Term (Inhalation)[3]	Oral LOAEL= 2.0 UF = 300	Plasma ChE Inhibition in females and RBC ChE Inhibition in males and female rats	Acute Neurotoxicity Study in Rats
Intermediate-Term (Inhalation)[2]	Oral LOAEL = 0.2 UF = 300	RBC ChE Inhibition in rats	13-Week Dietary Study in Rats
Long Term (Inhalation)[2]	None	The use pattern and exposure scenario does not indicate a need for long term risk assessment	

C. Considerations for special sensitivity in infants and children (FQPA)

On September 8, 1997, the HIARC met to evaluate the toxicology data base of coumaphos with special consideration for the developmental, reproductive, and neurotoxicity data. These data were re-evaluated in order to address the sensitivity of infants and children from exposure to coumaphos, as required by the FQPA. The FQPA requirement was not addressed in the reregistration eligibility document dated April 21, 1995. Developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity in young rats or rabbits following pre- or postnatal exposure to coumaphos, and comparable NOAELs were established for adults and offspring. The results of the two-generation reproduction study in rats showed no increased sensitivity in pups over adults. Based upon a weight-of-the-evidence consideration of the data base, the HIARC Committee determined that a developmental neurotoxicity study in rats is not required. However, the lack of acute and subchronic neurotoxicity studies was viewed as a data gap. As a result, the FQPA Safety Factor Committee determined that the 10X factor to account for enhanced sensitivity of infants and children should be reduced to 3X.

On May 11, 1999, the HIARC re-visited coumaphos in order to evaluate the acute and subchronic neurotoxicity studies in the rat. These studies were found to be acceptable and meet guideline requirements. Data gaps for acute and subchronic neurotoxicity studies in the rat have

[3]Oral values were selected; therefore, route-to-route extrapolation must be used (assume 100% inhalation absorption).

been adequately fulfilled. The FQPA Safety Factor Committee met on May 17, 1999 to re-evaluate the hazard and exposure data for coumaphos, and recommended that the FQPA Safety Factor be reduced to 1X in assessing the risk posed by coumaphos. The Committee concluded that the safety factor could be reduced to 1X for the following reasons:

(1) The toxicology database is adequate for coumaphos (the previous data gap has been fulfilled).

(2) There is no indication of increased susceptibility in rats or rabbits to coumaphos. In the developmental and reproductive toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

(3) The HIARC determined that a developmental neurotoxicity study in rats is not required.

(4) The dietary exposure assessment does not underestimate the potential exposure to infants and children from residues in food. No exposure to infants and children from residential sources is expected.

III. Exposure Characterization

A. Registered Uses

Coumaphos [0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2*H*-1-benzopyran-7-yl) phosphorothioate] is an organophosphorus acaricide registered primarily by Bayer Corporation (formerly Miles, Inc.) for direct application to cattle, goats, horses, sheep, and swine for the control of arthropod pests (including ticks, scabie mites, lice, face fly, horn fly, fly larvae, fleece worms, screw worms, sheep ked, and cattle grubs). The use on poultry has been canceled; tolerances on poultry and eggs have been proposed for revocation (Federal Register notice, 4/7/99). Technical coumaphos contains 93% active ingredient (ai) and is formulated as a formulation intermediate (25% ai), a dust (1% ai), a ready-to-use dust (5% ai), a wettable powder (26.3% ai), an emulsifiable concentrate (6.15% and 11.6% ai), a flowable concentrate (42% ai), and a pressurized liquid (3% ai). There are no registered uses of coumaphos on agricultural crops or in/around residences.

B. Dietary Exposure

Food Exposure

Tolerances have been established for the combined residues of coumaphos and its oxygen analog (O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl phosphate) in meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep, and in milk. [*Source: 40 CFR §180.189*]. Tolerances are set at 1.0 ppm in livestock tissues and 0.5 ppm in milk-fat. Although tolerances are still listed in the most recent CFR (revised July 1, 1998) for poultry (1.0 ppm) and eggs (0.1 ppm), the use of coumaphos on poultry (eggs) has been canceled and these tolerances are currently being revoked.

A tolerance reassessment was conducted in 1995 (J. Redden memo, 4/21/95). No changes to the established milk, sheep, cattle, horse, goat, and hog tolerances were required.

Anticipated residue values were calculated from field trial data for estimation of both acute and chronic dietary exposure (M. Metzger memo, 7/18/89). The anticipated residue values are still considered appropriate for dietary risk assessment purposes, with the exception of the chronic anticipated residue for beef fat, which has been revised to 0.072 ppm from 0.15 ppm (C. Olinger memo, 3/7/95).

In the HED RED Chapter for coumaphos, dated 4/21/95, storage stability data for animal tissue and milk were listed as outstanding. CBRS (Chemistry Branch Reregistration Support) has since determined that no additional animal tissue and milk storage stability data are required (C. Olinger memo, 8/9/95). The HED RED Chapter for coumaphos also stated that residues of coumaphos *per se* were found in cattle fat from the metabolism study at levels up to 2.5 ppm, when treated at an application rate which is less than the maximum rate for the ready-to-use, pour-on formulation. The registrant was asked to provide an explanation for the discrepancy between residue levels found in the dermal metabolism study and the magnitude of the residue studies. In a C. Olinger memo dated February 6, 1996, this discrepancy was attributed to application methods used in the metabolism study that were not typical of field use. The sampling of tissues in the metabolism study was not representative of typical slaughter practices which would likely involve considerable blending of the fat throughout the animal or with meat. The registrant adequately addressed CBRS concerns.

The USDA Food Safety and Inspection Service (FSIS) data from 1993-1997 showed that residues of coumaphos were found in beef fat, horse fat, and veal fat. In some cases, the residue levels (1.06 ppm-1.62 ppm) exceeded the established tolerance level of 1 ppm. However, the majority of the samples analyzed showed no detectable levels of coumaphos: 4 detects out of 4,500 beef fat samples (2 of which were above tolerance), and 14 detects out of 2,063 horse fat samples (4 of which were above tolerance). In a C. Olinger memo dated 9/26/95, it is stated that Bayer does not believe that the over-tolerance residues were a result of the U.S. Department of Agriculture's (USDA) treatment program. USDA's treatment program involves mostly dipping cattle in a coumaphos solution (0.3%), slaughtering them between one and six days after treatment, and analyzing samples of renal fat for residues of coumaphos. The treatment history prior to the USDA treatment is unknown. Furthermore, it is expected that residues of coumaphos would be reduced or removed through normal food preparation or processing, such as cooking meats or milk pasteurization (S. DeVito memo, 11/23/98).

Drinking Water Exposure

HED has calculated acute and chronic drinking water levels of comparison (DWLOCs) for exposure from coumaphos and its degradate coumaphoxon in surface and ground water. A DWLOC is the concentration of a pesticide in drinking water that is acceptable as a theoretical upper limit, in light of total aggregate exposure to the pesticide from food, water, and residential sources. Calculated DWLOCs are compared to the estimated environmental concentrations of a pesticide in drinking water (EECs), provided by the Environmental Fate and Effects Division (EFED). If the estimated concentrations of coumaphos in drinking water are less than HED's levels of concern for drinking water (i.e., if the EEC < DWLOC), exposure from coumaphos in

drinking water is not a risk of concern.

EFED used GENEEC as a Tier 1 screening-level model to provide an upper-bound estimate of pesticide concentration in surface water for comparison to the DWLOCs. GENEEC is a mechanistic model that represents a worst-case runoff scenario for pesticides in surface water. SCI-GROW was used as a Tier 1 screening-level model to provide an upper-bound estimate of pesticide concentration in ground water for comparison to the DWLOCs. SCI-GROW is an empirical model based on field data from prospective ground water studies. EFED does not have a model for estimating Tier 2 ground water concentrations for dietary risk assessment.

The acute and chronic DWLOCs for surface and ground water are shown in Table 2 below:

Table 2: Acute and chronic DWLOCs for surface and ground water

Acute Surface and Ground Water						
Population	**GENEEC (μg/L)**	**SCIGROW (μg/L)**	**aPAD (mg/kg/d)**	**Acute Food Exposure (mg/kg/d)**	**Acute Water Exposure (mg/kg/d)**	**$DWLOC_{acute}$ (μg/L)**
U.S. Population	2.2	17	0.007	0.00081	0.0062	220
Children (1-6)	2.2	17	0.007	0.0.0015	0.0055	55
Infants (<1 year)	2.2	17	0.007	0.00062	0.0064	64
Chronic Surface and Ground Water						
Population	**GENEEC (μg/L)**	**SCIGROW (μg/L)**	**cPAD (mg/kg/d)**	**Chronic Food Exposure (mg/kg/d)**	**Chronic Water Exposure (mg/kg/d)**	**$DWLOC_{chronic}$ (μg/L)**
U.S. Population	0.53[4]	17	0.0003	0.000056	0.00024	8.54
Children (1-6)	0.53	17	0.0003	0.00011	0.00019	1.93
Infants (<1 year)	0.53	17	0.0003	0.000022	0.00028	2.8

The maximum (acute) EECs in surface and ground water are less than OPP's levels of comparison for exposure from coumaphos in drinking water. Acute exposure from coumaphos in drinking water (surface and ground water) is not a risk of concern.

The average (chronic) EECs in surface water are less than OPP's levels of comparison for exposure from coumaphos in drinking water; however, average (chronic) EECs in ground water are greater than OPP's levels of comparison for the U.S. general population, children 1-6, and infants (<1 year). Since EFED does not have a model for estimating Tier 2 ground water concentrations, no further refinements can be made.

Limitations to, and uncertainties accompanying, the drinking water data include a lack of

[4]The GENEEC model estimated 56-day (average) concentration can be divided by a factor of 3 prior to comparison with the $DWLOC_{chronic}$. In this case, (1.6 μg/L) / 3 = 0.53 μg/L.

acceptable environmental fate data for the parent coumaphos and its degradate, a lack of information on the concentration of degradation products in the bioremediated coumaphos solution, and a lack of information regarding the land application rate of bioremediated coumaphos and coumaphoxon from cattle dips.

C. Non-Dietary Exposure

Occupational

Coumaphos can be applied with high and low pressure hand wands, foam spray cans, dip vats, mechanical dusters, shaker cans, dust bags, ready-to-use dust containers, and back oil rubbers. The label application rates range from 0.005 to 0.076 lbs. ai per gallon of spray or dip, 0.000625 to 0.013 lbs. ai per animal for dust application, 0.000625 to 0.019 lbs. ai per day for aerosol cans or ready-to-use dust containers, and 0.042 lbs. ai per 1000 square feet of swine bedding treatment, depending upon the animal treated. The majority of coumaphos is used on beef cattle. HED has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with coumaphos.

All exposure scenarios, except for mixing/loading liquids and wettable powders for the dip vat use on cattle, are short-term exposure duration only (less than seven days). Mixing/loading liquids and wettable powders for the cattle dip vat use is considered an intermediate-term exposure scenario (seven days to several months), since the quarantine areas located along the Texas/Mexican border are staffed by federal workers on a continual basis, and mixers/loaders are assumed to be exposed to coumaphos more than seven days per year. Exposure to the applicator from dip vat use was only assessed for application to sheep and goat, because HED believes that there is minimal exposure to applicators who dip cattle. Cattle are herded through the dip vat, and then proceed directly to a holding pen where they dry, resulting in minimal exposure to the applicators.

Mixing/loading liquids and wettable powders for cattle dip vat use may not be considered a chronic exposure since the USDA workers dip only the local U.S. cattle and are removed from dipping operations if their cholinesterase levels reach a level of concern. Since there is no quantitative data, such as the number of cattle dipped per day, the number of days dipping takes place, etc. to determine whether there is a chronic exposure to dip vat workers in the quarantine area, HED requests more information on quarantine dipping practices to clarify the duration of exposure. The routes of exposure for all exposure scenarios are dermal and inhalation.

Chemical-specific data for assessing human exposure during pesticide handling activities were not submitted to the Agency in support of the reregistration of coumaphos. It is the policy of HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.

Occupational Post-Application

No registered uses of coumaphos fall under the Worker Protection Standard (WPS). EPA

has established the following for all non-WPS occupational uses of coumaphos end-use products: "Do not contact treated animals until sprays have dried and dusts have settled on the coat."

HED has determined that there is likely to be some exposure to people contacting treated animals immediately after application is complete. No exposure data are available to assess risk from such contact. However, HED has determined that the amount of exposure is likely to be substantially lower than the exposure to handlers, since coumaphos is applied directly to livestock. Therefore, no post-application exposure data are required.

Residential

Coumaphos is not intended for use in/around residences.

IV. Risk Assessment/Characterization

An uncertainty factor (UF) of 100 was applied to the risk assessment to account for inter- and intraspecies variation. An extra UF of 3X was applied to the acute dietary risk assessment and the short-and intermediate-term inhalation assessments for lack of a NOAEL. The FQPA safety factor was reduced to 1X.

Both short- and intermediate-term dermal and inhalation endpoints were based on cholinesterase inhibition; therefore, it is appropriate to combine the dermal and inhalation Margins of Exposure (MOEs). Since the dermal and inhalation acceptable MOEs are different (100 and 300, respectively) an Aggregate Risk Index (ARI)[5] was calculated, as opposed to a total MOE. To be acceptable, the ARI must be equal to, or greater than, one. For scenarios where there were no inhalation data, the dermal and inhalation MOEs were not aggregated, and the acceptable MOE remains 100. It is not considered appropriate to apply the FQPA safety factor to occupationally exposed workers.

Dietary

DEEM™ (Dietary Exposure Evaluation Model), based on food consumption data from the USDA Continuing Survey of Food Intake by Individuals (CFSII) from 1989-92, was used to estimate acute and chronic dietary exposure to coumaphos. DEEM™, which replaces DRES (used in the dietary exposure assessment for the 1996 Coumaphos RED), is used to estimate exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups, and assumes uniform distribution of coumaphos in the food supply. A summary of the residue information considered in this acute and chronic dietary analysis is included in attachment 3.

<u>*Acute risk:*</u> The acute analysis for coumaphos is a refined estimate of dietary exposure, incorporating anticipated residues (M. Metzger memo, 7/18/89) and percent livestock treated

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[5] $ARI = 1/[(1/(\text{Dermal } MOE_{calculated}/\text{Dermal } MOE_{acceptable})) + (1/(\text{Inhalation } MOE_{calculated}/\text{Inhalation } MOE_{acceptable}))]$

information. The percent of the acute PAD utilized for the highest exposed subpopulation (children 1-6 years old) at the 95th percentile is 21%.

Based on calculated risk estimates, the acute dietary risks associated with the use of coumaphos do not exceed the acute PAD for any of the DEEM™ population subgroups. The results of the acute analysis are shown in attachment 4.

Chronic risk: The chronic analysis for coumaphos is a refined estimate of dietary exposure, incorporating anticipated residues (M. Metzger memo, 7/18/89) and percent livestock treated information.

Based on calculated risk estimates, the chronic dietary risks associated with the use of coumaphos do not exceed the chronic PAD for any of the DEEM™ population subgroups. The percent of the chronic PAD utilized for children 1-6 years old (the highest exposed subpopulation) is 43%. The results of the chronic analysis are show in attachment 4.

Total Dietary (Aggregate)

An aggregate risk assessment (food + water + residential) for acute and chronic exposure from coumaphos is appropriate for exposure from dietary and drinking water sources only. There are no residential uses of coumaphos; therefore, residential exposure is not included in the aggregate risk assessment.

i. Acute

The contribution of food alone to aggregate acute risk represents 21% of the aPAD for the highest exposed subpopulation (children 1-6), leaving 79% of the aPAD available for exposure through drinking water. The estimated maximum peak concentrations of coumaphos in surface water (2.213 μg/L) and ground water (17.202 μg/L) are below HED's levels of comparison for exposure from coumaphos in drinking water as a contribution to aggregate acute dietary risk.

ii. Chronic

The contribution of food alone to aggregate chronic risk represents 43% of the cPAD for the highest exposed subpopulation (children 1-6), leaving 57% of the cPAD available for exposure through drinking water. The estimated total coumaphos residue concentration in ground water used as drinking water (17.202 μg/L) exceeds HED's level of comparison for exposure from coumaphos in drinking water as a contribution to aggregate chronic dietary risk.

However, SCI-GROW is a conservative screening model that provides an upper-bound concentration estimate of coumaphos in ground water, and uses the highest labeled application rate for coumaphos to provide a worst-case estimate.

Uncertainties associated with EFED's Tier 1 drinking water assessment include a lack of acceptable environmental fate data for coumaphos and its degradate coumaphoxon (as a conservative estimate, it is assumed that coumaphoxon is persistent and highly mobile); a lack of information regarding the land application rates of coumaphos and coumaphoxon in bioremediated cattle dips; and a lack of information on the concentration of degradation products in the bioremediated coumaphos solution.

Occupational

The short-term dermal and inhalation NOAELs were both based on cholinesterase inhibition; therefore, the MOEs were combined to identify a total short-term MOE, **except** when there was no inhalation data (which occurred when studies lacking inhalation data were used, i.e. a shaker can). The intermediate-term dermal and inhalation NOAELs were also based on identical endpoints (cholinesterase inhibition); therefore, the MOEs were combined to identify a total intermediate-term MOE. However, since the dermal and inhalation acceptable MOEs are different (100 and 300, respectively), an ARI was calculated in place of a total MOE. To be acceptable, an ARI must be equal to, or greater than, one. For the scenarios where there was no inhalation data, and thus dermal and inhalation MOEs were not aggregated, the acceptable MOE remains 100. Chronic endpoints were not selected because coumaphos may not be considered to have exposures of chronic durations.

All calculated short- and intermediate-term ARIs are a risk of concern (ARIs < 1) **at the baseline level** (long pants, long-sleeved shirt, no gloves, open mixing/loading). The calculations of short-term, dermal-only risk for scenarios that lack inhalation data at baseline indicate that dermal MOEs are less than 100 for all assessed exposure scenarios, **except** the following:

1) Applying dusts with shaker can for cattle, horses, swine, and swine bedding.

The following short-term exposure scenarios' calculated ARIs are a risk of concern (less than 1) **at the additional PPE level** (personal protective equipment). PPE includes a double layer of clothing (i.e. long pants, long-sleeved shirt, coveralls, and a chemically resistant apron) for dermal exposure and a dust/mist respirator for inhalation exposure.

1) Mixing/loading wettable powders for hydraulic type dip vats on cattle, goats, and sheep.

2) Mixing/loading wettable powders for swim type dip vats on cattle, sheep, and goats.

3) Applying liquids for high pressure hand wand on cattle and horses.

All calculated intermediate-term ARIs are a risk of concern (less than 1) at the additional PPE level. The calculations of short-term, dermal-only risk for scenarios that lack inhalation data indicate that all dermal MOEs are greater than 100 at the additional PPE level **except** for the following:

1) Applying liquids with hydraulic type dip vats for goats and sheep.

2) Applying liquids with swim type dip vats for goats and sheep.

3) Loading/applying dusts with a mechanical duster on cattle, horses, swine, and swine

bedding.

The current methods used to apply coumaphos do not appear to incorporate engineering controls. The Agency seeks information on any current or feasible engineering control to mitigate risk to handlers, such as closed mixing/loading systems or automated application spray systems.

Overall, there is low to high confidence in the PHED unit exposure data, depending on the exposure scenario. The exposure scenarios and corresponding risks are presented in Tables 4 and 5 of the attached Occupational Risk Assessment Chapter.

There were no available data to assess exposure to the following exposure scenarios:

1) Loading dusts into bags

2) Inhalation exposure from applying liquids with hydraulic type dip vats on sheep and goats.

3) Inhalation exposure from applying liquids with swim dip vats on sheep and goats.

4) Applying a ready-to-use dust.

5) Inhalation exposure from applying dusts with a shaker can.

6) Inhalation exposure from loading/applying dusts with a mechanical duster.

Cumulative Risk

The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, coumaphos and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.

Attachments:

Attachment 1: HIARC report, N. Paquette memo, 5/12/99
Attachment 2: HIARC report, N. Paquette memo, 6/25/99
Attachment 3: Dietary Exposure Analysis, C. Jarvis and S. Mason memo, 6/1/99
Attachment 4: Dietary Exposure Analysis (ADDENDUM), C. Jarvis and S. Mason memo, 7/9/99
Attachment 5: FQPA report, B. Tarplee memo, 6/1/99

Attachment 6: Occupational Exposure Assessment, R. Sandvig memo, 6/30/99
Attachment 7: Tier 1 Drinking Water Assessment, J. Hetrick memo, 6/16/99